APPROVALS

Meaning / Title	Signature	Date
Revision B: Updated revision to align with ELP Template 047254. Add equipment E86724-100 to the Scope and the Equipment Description section. Add photos of equipment E86724-100 to section 2 “Machine Shut down Process”.		
Author: Manufacturing Engineer	*Mateo, Carlos-mateoc*	*05-Dec-2018 13:45 (GMT -0600)*
Approvers: EHS	*Gonzalez Ruiz, Ariel-g042035*	*14-Dec-2018 13:51 (GMT -0600)*
Sterilization Associate	*Lara Munoz, Andres-g021476*	*17-Dec-2018 06:39 (GMT -0600)*
Quality Engineer	*Bonilla, Lourdes-bonill1*	*14-Jan-2019 15:19 (GMT -0600)*
End of Approvals		

ELP56204
Rev B

ELP for 100% ETO STERILIZATION CHAMBER

Purpose	To provide specific, written guidance for lockout-tagout authorized personnel on how to de-energize, isolate, and reenergize the equipment; and to prevent the unexpected start-up or release of energy that could result in injury to employees.
Scope	This procedure applies to personnel who perform service or maintenance on equipment, including any outside contractors, at Boston Scientific, E-69094-100 and E86724-100.
Records Created	None
References	005505 Equipment Lockout Policy 006609 Writing and Authorizing Equipment Procedures 006656 Hot Work Permit, Red Tag and Lockout/Tagout – CLONMEL FACILITY MAINTENANCE ONLY 045654 Temporary Operational Interruptions and Troubleshooting Operations 070354 Global Workflow User Assistance Guide 005508 Laser Safety
Terminology	Refer to 005505 Equipment Lockout Policy Clonmel Facility Maintenance: refer to 006656 Hot Work Permit, Red Tag and Lockout/Tagout St. Paul: refer to 045654 Temporary Operational Interruptions and Troubleshooting Operations
Description of Change	Available at the end of the document.

1. Equipment Description

Machine Description:	Getinge Sterilizer	Model #:	1250X1500X1500-1
Energy Sources:	AC Voltage, Steam, Soft water, Compressed Air and EtO	Magnitude:	120, 480 VAC, 40, 60 and 80 psi

Figure 1: Getinge Sterilizer (E69094-100)

Machine Description:	Getinge Sterilizer	Model #:	1250X1500X3000
Energy Sources:	AC Voltage, Steam, Soft water, Compressed Air and EtO	Magnitude:	120, 480 VAC, 40, 60 and 80 psi

Figure 2: Getinge Sterilizer (E86724-100)

2. Machine Shut down Process

Step 1. Notify affected employees of pending shut down and application of lockout/tagout devices (operators, area personnel).

Step 2. Switch the main breaker to "Off" position and lock out with Group #2 LO Devices.

Step 3. Turn the Ball Valve for the nitrogen to off position and lock out with Group #16 LO Device.

Step 4. Turn the Ball Valve for the compress air to the off position and lock out with Group #16 LO Device.

Step 5. Turn the Ball Valve for the steam to the off position and lock out with Group #16 LO Device.

Step 6. Turn the Ball Valve for the EtO and nitrogen on the tank to the off position and lock out with Group #16 LO Device.

Step 7. Turn off main breaker for the steam generator; lock out with Group #11.

Step 8. Relieve, restrain, block, disconnect, or otherwise render safe all stored or residual energy from the system.

Step 9. Verify equipment is disconnected from the energy source(s) and is in a zero energy state. Check that no personnel are exposed.

Step 10. Verify isolation by activating the normal operating controls. Caution: return control(s) to neutral or OFF position after verification.

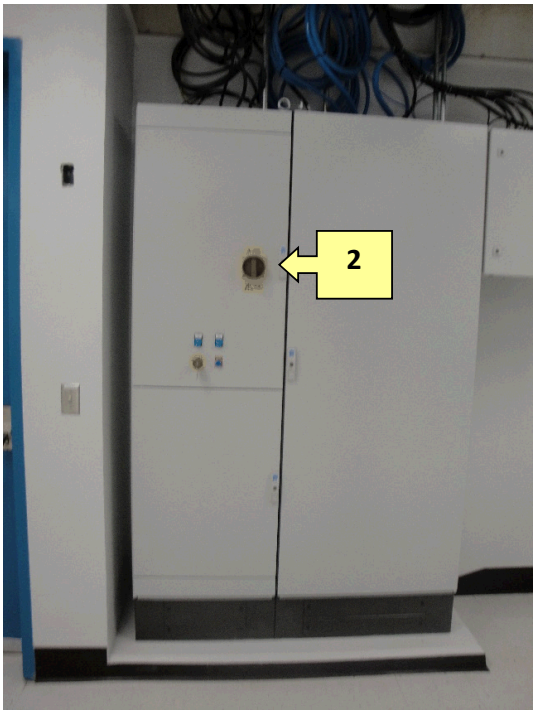


Figure 3: Sterilizer E69094-100 (Main Breaker)

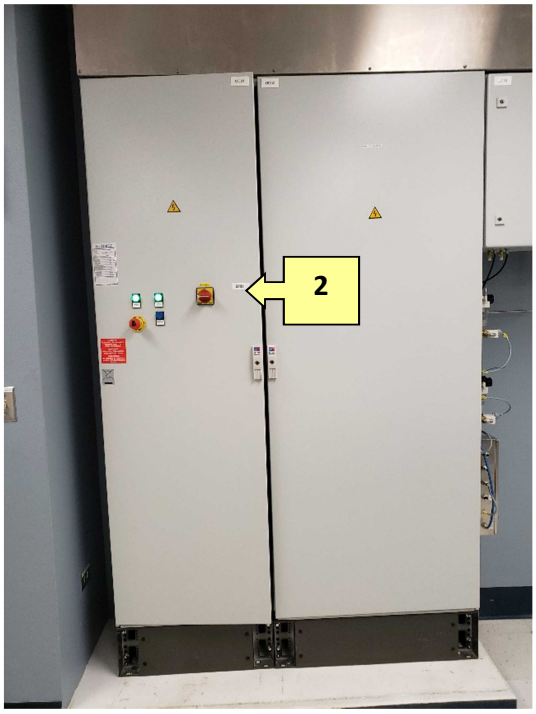


Figure 4: Sterilizer E86724-100 (Main Breaker)

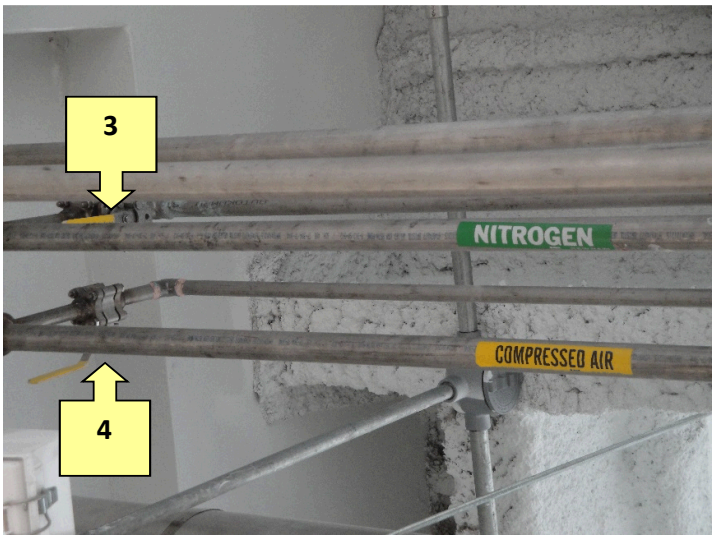


Figure 5: Sterilizer E69094-100 (Compressed Air and Nitrogen)

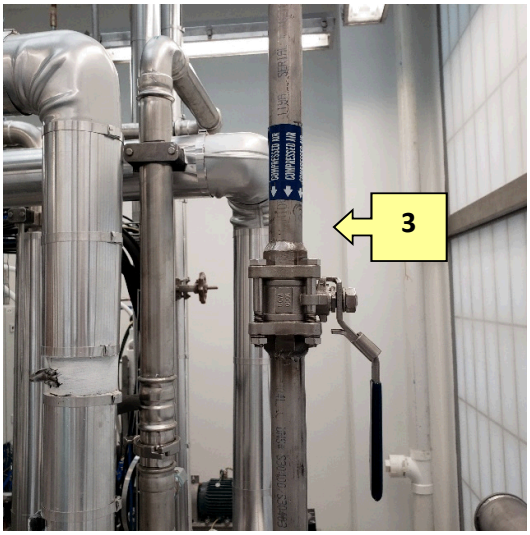


Figure 6: Sterilizer E86724-100 (Compressed Air)

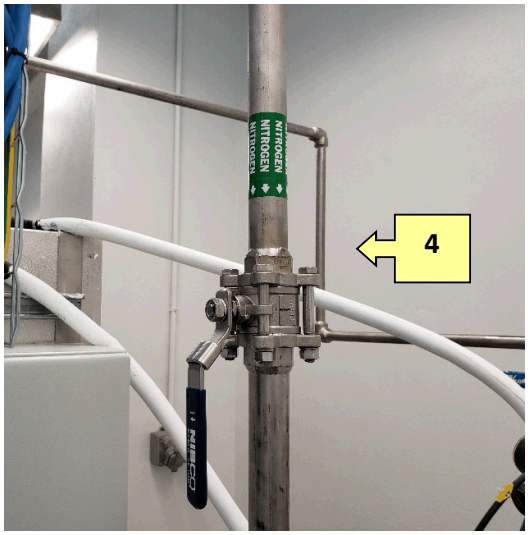


Figure 7: Sterilizer E86724-100 (Nitrogen)

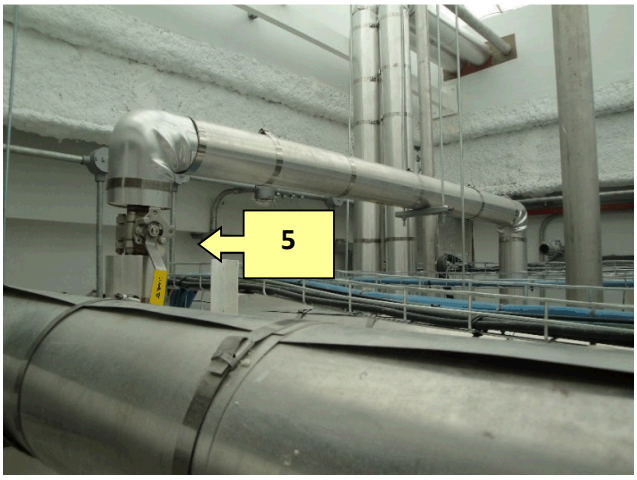


Figure 8: Sterilizer E69094-100 (Steam)

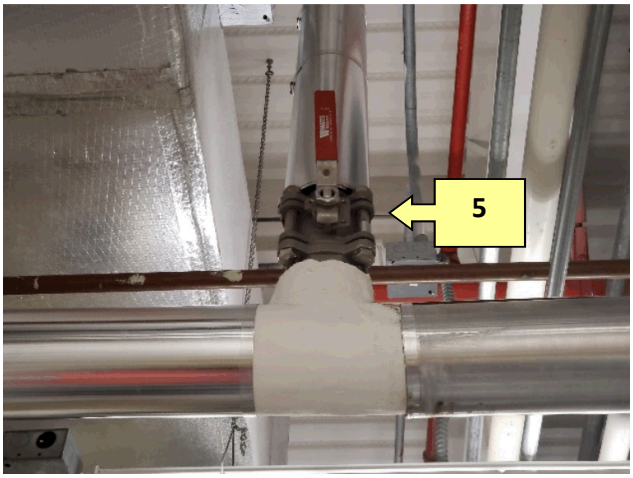
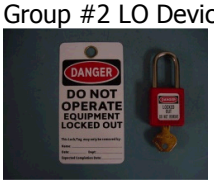


Figure 9: Sterilizer E69094-100 (Steam)

Group #2 LO Device



Lock and Tag

Group#11 LO Device

Circuit Breaker Lockout for single, double or triple pole

Group LO #16

Ball Valve Lockout

3. Release from Lockout/Tagout Process

Step 1. Notify employees in area of release from lockout/tagout. Inspect area to ensure all nonessential items have been removed, and that the machine is operationally intact.

Step 2. Ensure all employees in work area are removed or safely positioned.

Step 3. Remove lockout/tagout (group #1 device) Note: Each authorized employee shall remove the lockout/tagout device that they applied as stated in Section 4, Authorization.

Step 4. Turn switch to Right, into the "ON" position, to reenergize the system and return equipment to service.

4. Authorization

Only Boston Scientific Facilities maintenance technicians trained in lockout/tagout procedures or authorized employees trained in lockout/tagout procedures are authorized to install lockout/tagout devices in accordance with company procedures. Only the installer or the maintenance leader shall remove lockout/tagout devices.

Failure to comply with established procedures may result in disciplinary action or termination.

Description of Change

Revision	Description of Change
B	Updated revision to align with ELP Template 047254. Add equipment E86724-100 to the Scope and the Equipment Description section. Add photos of equipment E86724-100 to section 2 "Machine Shut down Process".
A	Initial Release. ELP was executed to ensure instructions could be executed as written.